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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 4866-0101PUS1 2121 10/821,925 04/12/2004 Xiabin Jing EXAMINER 2292 7590 12/27/2005 BIRCH STEWART KOLASCH & BIRCH GHERBI, SUZETTE JAIME J **PO BOX 747** PAPER NUMBER ART UNIT FALLS CHURCH, VA 22040-0747

3738

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)				
Office Action Summers	10/821,925	JING ET AL.				
Office Action Summary	Examiner	Art Unit				
	Suzette J. Gherbi	3738				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 03 Oc	ctober 2005.					
,	action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-5,7,8,10 and 12</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-5,7,8,10 and 12</u> is/are rejected.						
7) Claim(s) is/are objected to.						
of the subject to restriction and/or election requirement.						
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>03 October 2005</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	-(d) or (f)				
a) ☑ All b) ☐ Some * c) ☐ None of:						
1.⊠ Certified copies of the priority documents	s have been received.					
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau	•					
* See the attached detailed Office action for a list of the certified copies not received.						
222 and addition defined defined definition of the definition depicts flot received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Tupe: Notice of Informal Patent Application (PTO-152)						
Paper No(s)/Mail Date	6) Other:					
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#### **DETAILED ACTION**

1. Applicant's amendments filed 10/3/05 have been received in application serial number 10/821,925. Claims 6, 9 and 11 have been canceled and claim12 has been added.

#### Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-5, 7-8, 10, and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended the claim to state "...wherein the sent is formed in multiple parts.." however there is not mention in the specification of forming the stent from multiple parts.

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### Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 1-6 and 8-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over A. Bowen 2,127,903 in view of Datta et al. 6,338,739. Bowen discloses the invention as claimed noting figures 1-7a comprising; A biodegradable common bile duct stent; wherein the stent is thin; wherein various parts (5-6 collars) of the stent are 1-3 times of the inner diameters of the corresponding parts of the common bile duct; wherein the stent can be manufactured and tailored to fit varying lumens (col. 4, lines 39-43). However Bowen does not specify that the biodegradable material is polymeric with the inclusion of radiopaque components. Datta et al. teaches that stent for use in the biliary tract [col. 1, lines 20) has been known to be manufactured from polymeric biodegradable materials [col. 3, lines 40-67); having lengths from between 10mm-100mm and widths/diameters from between 2mm-25mm (col. 8, lines 4-7) and extrusion blowing processes of manufacture ( (it is noted here that claim 11 is being treated as a product by process claim see MPEP 2113 and 716.01). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize biodegradable polymeric materials because there would have been less of a chance of rejection from the use of degradable animal tissue; it would have been

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obvious to utilize a radiopaque component in order for the physical to track/locate/monitor the device after implantation.

### Allowable Subject Matter

6. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Response to Arguments

7. Applicant's arguments filed 10/3/05 have been fully considered but they are not persuasive. Applicant has amended the claims form to for better grammatical clarifications and goes on to point out what their invention comprises. Applicant also states that Bowen is made of absorbable animal tissues and various kinds of surgical tubes and not biodegradable synthetic polymers. The examiner disagrees with applicant and realizes that Bowen's patent does not disclose some of the materials as claimed, which is why a 103 rejection was presented above. For example, applicant states that the Bowen device is related to surgical tubes. This is exactly what claim 1 states "... a tube structure..", applicant states that there device is for CBD (common bile ducts) Bowen states in page 2, lines 45-47 that the device is used in the common bile duct. Applicant goes on to contend that Datta only discloses bi-component filaments,

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which are wound into tubes. The device of Datta was not utilized for the structure, rather used in a 103 rejection to teach the materials biodegradable polymers; barium sulfate which is a radiopaque material and lengths as claimed. Therefore in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation comes from the fact that both devices disclose that the materials can be utilized in the common bile duct and are capable of performing the functions.

#### Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Suzette J. Jackson whose work schedule is Monday-

Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

10. The fax phone numbers for the organization where this application or proceeding

is assigned are 703-872-9306.

11. Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is 703-308-

0858.

Suzette J-J Gherbi

Contract of Merce

19 December 2005

## REPLACEMENT SHEET

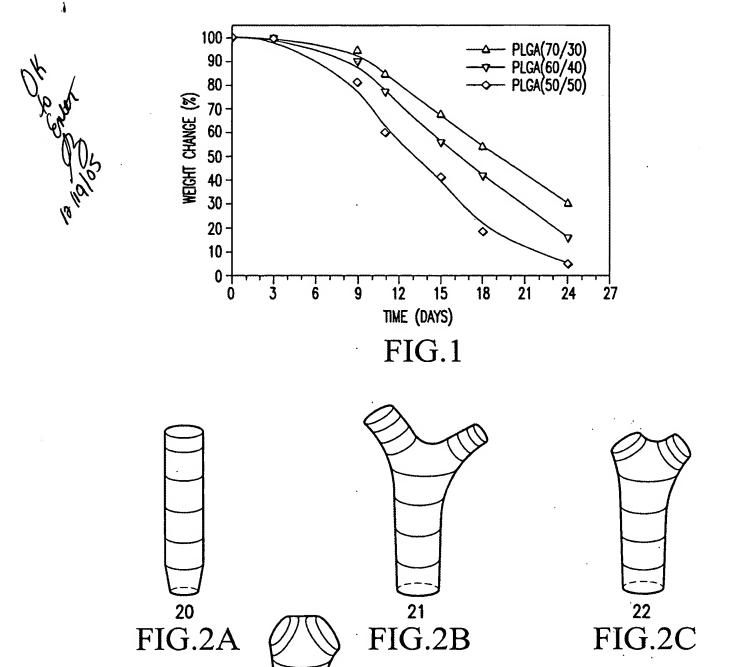


FIG.2D

FIG.2E

